A photograph of a woman with long brown hair, wearing a blue halter top, smiling and holding a baby. The baby is wearing a white onesie and has its hand near its mouth. The background is plain white.

OvaCue[®]

FERTILITY MONITOR *mobile*

Owners Manual

Welcome

Thank you for purchasing the OvaCue Mobile Fertility Monitor!

Recommended by fertility specialists, this convenient, easy to use fertility monitor provides up to seven days advance notice of ovulation with 98% accuracy.

We are pleased that you are among the thousands of couples using the OvaCue Mobile to aid in conception.



www.ovacue.com

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The OvaCue Mobile Fertility Monitor was developed to assist in conception. It must be used in accordance with the instructions contained in this manual. Use of this product does not guarantee success in achieving pregnancy. OvaCue Mobile is an in vitro diagnostic medical device designed for home use. Store in a dry place at room temperature. Keep out of the reach of children. Ovacue Mobile is not intended to be used to prevent pregnancy.

The Key to Conception: Understanding Your Cycle

You have decided that now is the time in your life to have a baby, but you might be learning that becoming pregnant is not as easy as you once thought. The OvaCue Mobile Fertility Monitor may help to increase your chances of conceiving by predicting your most fertile days up to seven days in advance. But, before you begin using your OvaCue Mobile, it is important to understand how your menstrual cycle works.

The menstrual cycle is the process during which your body prepares for pregnancy. It is regulated by a complex interaction of several key hormones, and for most women, lasts between 24 and 35 days. Your cycle begins with menstruation (day 1 of your cycle is the first day of your menstrual period), with ovulation occurring sometime close to the midpoint of your cycle.

Ovulation is the process through which an egg is released from the ovary. Within the ovaries, each egg is stored in a fluid-filled cavity called a follicle. While both ovaries store many follicles, only one follicle (called the dominant follicle) is selected each month to release an egg. The maturation process of the dominant follicle occurs approximately 5-7 days before ovulation.

As the dominant follicle matures, the amount of estrogen produced in your body increases. At the same time, luteinizing hormone (LH) is produced and stored in the anterior pituitary gland. Just prior to ovulation, the anterior pituitary gland secretes a surge of LH, which causes the wall of the dominant follicle to weaken and rupture, thereby releasing the egg and propelling it into the opening of the nearby fallopian tube.

Once the egg is released from the follicle, the follicle cells transform into the corpus luteum, a glandular structure that secretes large amounts of progesterone. If the egg is fertilized (which must occur within 24 hours after ovulation), increasing amounts of progesterone are released. Progesterone acts to build the uterine lining for implantation of a fertilized egg and prevents menstruation. If conception does not occur, the corpus luteum will disintegrate towards the end of the menstrual cycle, progesterone levels will drop rapidly, and menstruation will occur.

By tracking changes in the concentration of electrolytes in your saliva, OvaCue Mobile detects the hormonal changes that coincide with the maturation of the dominant follicle, and uses this information to predict the days you will be most fertile. Using the data collected with the vaginal sensor, OvaCue Mobile detects the surge in estrogen that occurs just prior to ovulation, and the shift to progesterone dominance that occurs at ovulation. This information allows OvaCue Mobile to help confirm the date of ovulation.

Description of Parts



Mobile Adapter



Vaginal Sensor



Oral Sensor

How OvaCue Mobile Works

The OvaCue Mobile Fertility Monitor predicts ovulation up to seven days in advance using the patented Electrolyte Method™ — a technique that has been demonstrated to be 98.3% accurate in predicting ovulation.

Here's how it works: OvaCue Mobile consists of a mobile adapter, oral sensor, and vaginal sensor. The mobile adapter plugs directly into your smartphone, and the oral and vaginal sensors plug into the adapter. OvaCue Mobile works in conjunction with the OvaGraph mobile app - a FREE download from your App Store. Throughout your menstrual cycle, the electrolyte (minerals such as sodium and potassium) levels in your saliva and cervical mucus fluctuate as the hormone levels in your body change. Starting on Cycle Day 2, you will use the oral sensor each morning to measure the electrolyte levels in your saliva. The OvaGraph app will store the information gathered from these oral readings, track the changes in electrolyte levels in your saliva during your cycle, and process this information to precisely define your time of peak fertility.

Pinpoint Your Fertile Window!

Look for the blue days!

About a week before ovulation occurs, OvaCue Mobile will identify a Cue Peak in your oral readings. **The Cue Peak is defined as a high oral reading followed by two lower oral readings.** Once your Cue Peak is detected, which coincides with the maturation of the dominant follicle, OvaCue Mobile can then predict, several days in advance, the day you will likely ovulate. This advance notice of ovulation will give you the best possible chance of conception. OvaCue Mobile will display your peak fertility days indicating possible fertility to high fertility using light to dark blue colors.

Look for the pink day!

Once you begin using the vaginal sensor, OvaCue Mobile tracks changes in the electrolyte levels in the cervical mucus, which allows the monitor to detect the switch from estrogen to progesterone dominance that accompanies ovulation. When this shift occurs, you will see an increase in the vaginal readings (called the Vaginal Rise) and a pink day will appear. After the pink day is displayed, we expect to see the vaginal readings remain elevated to indicate ovulation was successful.

	White: indicates not fertile
	Light blue: indicates possible fertility
	Medium blue: indicates high fertility (good day for intercourse)
	Dark blue: indicates highest fertility (best day for intercourse)
	Pink: indicates possible ovulation
	Purple: indicates possible ovulation (see page 15 for more info)
	Gray: indicates no readings were saved
	Yellow: Error

IMPORTANT: For the best chance of conception, plan intercourse for any blue, pink, or purple days.

Getting Started

IMPORTANT: You must start using your OvaCue Mobile on the second day (Cycle Day 2) of your menstrual period, or by Cycle Day 4 at the latest. Until then, take some time to familiarize yourself with how your OvaCue Mobile works.

To begin using your OvaCue Mobile, please download the OvaGraph app from your App Store. Follow the set-up guide upon opening the OvaGraph app. You will need to have the following information ready:

- Current cycle day (remember, this **MUST** be a number between 1 and 4)
- Your average cycle length (the number of days between the start of one menstrual period to the day before the start of your next period, take an average of your previous 3 cycles)
- Cycle day you start fertility medications*

The OvaGraph app will store all of your cycle information and data.

*If you have been prescribed an ovulation stimulation medication (for example, Clomid™ or Femara™) please enter the cycle day that you will begin taking the medication. If you are not taking a prescription ovulation stimulation medication, leave the setting at 0.

Oral Readings

- Start taking your oral readings on Cycle Day 2, or by Cycle Day 4 at the latest.
- When taking an oral reading, place the sensor in your mouth, pressing it on your tongue with the silver sensors facing down.
- Take your oral readings first thing in the morning, about the same time every day.
- Take your oral readings before you eat, drink, smoke, or brush your teeth. Putting anything in your mouth before you take your reading will stimulate your salivary glands to produce more saliva, which will impact the electrolyte levels in your saliva and affect the reading.
- Take your oral readings every day until you have confirmed ovulation.
- Don't take more than one reading on the same day. If you do, the readings may be quite different and could impact the prediction.
- Don't miss a reading. Depending on which cycle day is missed, OvaCue Mobile may not be able to detect the trends it is looking for and may not provide an accurate prediction.
- Don't use sodium based antacids from Cycle Day 1 through ovulation.
- Clean the oral sensor with mild soap and water after each use.

Vaginal Readings

- Take your vaginal reading every day, starting immediately after menstruation has ended and until your next cycle begins.
- Take your vaginal reading at about the same time every day. Be sure to pick a time that will allow consistency.
- Take your reading before intercourse, or at least eight hours after.
- When taking your vaginal reading, insert the vaginal sensor into your vagina until you feel it touch the cervix, then pull it out slightly (approximately $\frac{1}{4}$ to $\frac{1}{2}$ inch) and tilt the handle upward slightly.
- Don't take the vaginal readings after midnight.
- Don't miss a reading. Missing too many readings before ovulation may result in inaccurate interpretation.
- Don't take more than one reading per day. If you do, the reading may be quite different and could impact the prediction.
- Clean the vaginal sensor with mild soap and water.

What Do The Numbers Mean?

The OvaCue Mobile Fertility Monitor uses the patented Electrolyte Method™ to measure changes in the electrolyte levels in your saliva and cervical mucus. These characteristic changes signal the onset and completion of ovulation. As your body moves through its monthly cycle, the levels of various hormones circulating in your body go up and down, and these hormonal fluctuations produce changes in the electrolyte characteristics of your saliva and cervical mucus. Using measurements obtained from the oral and vaginal sensors, OvaCue Mobile produces a numerical reading that reveals the relative trends in electrolyte levels. This allows OvaCue Mobile to identify when the hormonal changes that signal ovulation have occurred. When interpreting the numbers, it is important to remember that there is no predefined “normal” range into which your readings should fall, and readings will vary from person to person and from cycle to cycle.

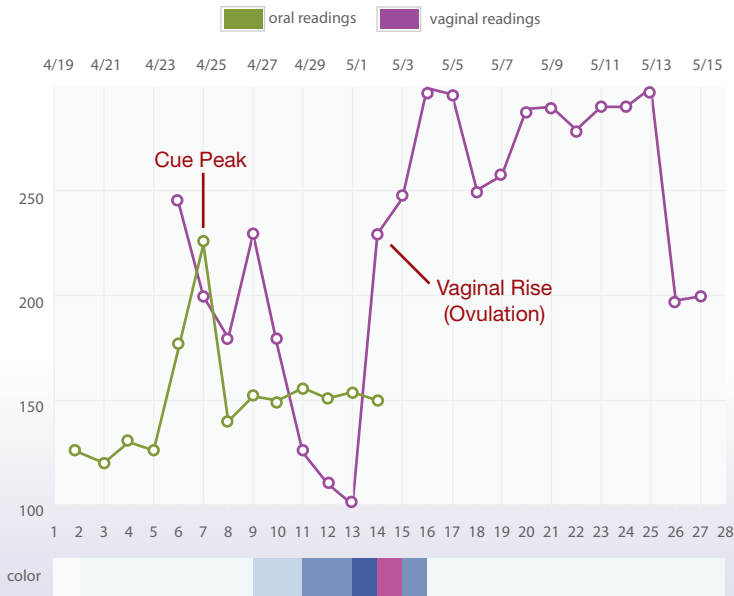
Oral readings:

About a week before ovulation occurs, a high oral reading followed by two lower oral readings will be detected, which is called the Cue Peak. Once the Cue Peak is detected, OvaCue Mobile can then predict, several days in advance, your most fertile days.

Vaginal readings:

OvaCue Mobile uses data collected by the vaginal sensor to track changes in the electrolyte levels in the cervical mucus. This allows the monitor to detect the estrogen surge that occurs just prior to ovulation, and the subsequent shift from estrogen to progesterone dominance that coincides with ovulation. In the days just prior to ovulation, your vaginal readings will be relatively low. Low vaginal readings reflect high estrogen levels, and indicate high fertility. Once ovulation occurs, your vaginal readings will increase, indicating the shift to progesterone dominance and the end of your fertile window.

Graph of Typical 28 Day Cycle



Sample chart from www.OvaGraph.com

Understanding the Purple Box

With the vaginal sensor, OvaCue Mobile tracks changes in the electrolyte levels of the cervical mucus, which allows the monitor to detect the shift from estrogen to progesterone dominance that accompanies ovulation. When this shift occurs, you may see an increase in the vaginal readings (called the Vaginal Rise) and your fertility prediction will change to pink. After the monitor detects a rise in the vaginal readings, it will expect the vaginal readings to remain elevated, which confirms that ovulation occurred successfully and that you have entered the luteal phase of your cycle.

If, after the Vaginal Rise (pink day), OvaCue Mobile detects a dip in your vaginal readings, and then a subsequent rise in your vaginal readings, you will see the purple fertility prediction appear. Because both the pink and purple days can represent ovulation, it will be necessary to do some data interpretation to determine which day represents the day that you actually ovulated. The appearance of the purple day suggests that your vaginal readings for the current cycle did not follow the typical pattern of remaining elevated after the first Vaginal Rise. There are a number of possible explanations for why vaginal readings might dip, and then increase again, including hormonal fluctuations or the occurrence of secondary fertility (multiple follicular stimulation). For more information about the purple day and secondary fertility, please contact Customer Service or visit www.ovacue.com.

Frequently Asked Questions

When should I begin intercourse?

OvaCue Mobile will predict your fertile window and display your most fertile days using light to dark blue colors. When you see your fertile window populate, we recommend you plan intercourse every other day on the light blue days, and daily on the medium blue and dark blue days. It is also recommended that you have intercourse on the day of ovulation, displayed with a pink or purple day.

What does OvaCue Mobile measure?

It measures the change in electrolyte levels in saliva and cervical mucus that signal the onset and completion of the ovulatory process. As your body moves through its monthly cycle, the levels of various hormones circulating in your body go up and down, and these hormonal fluctuations produce changes in the electrolyte characteristics of your saliva and cervical mucus. Using measurements obtained from the oral and vaginal sensors, OvaCue Mobile produces a numerical reading that reveals the relative trends in electrolyte levels. This allows OvaCue Mobile to identify when the hormonal changes that signal ovulation have occurred.

Can I use OvaCue Mobile while taking Clomid?

Yes. OvaCue Mobile can be used by those taking ovulation stimulating medications, including Clomid™ (Clomiphene Citrate) or Femara™.

What do I do if I continue to receive an over 400 reading with either sensor?

We expect readings to fluctuate from one day to the next and for all readings to be under 400. If you continually receive an over 400 reading, or are concerned with your range of values, please contact customer service at support@ovagraph.com.

Do I have to take readings all month?

To have a full picture of your cycle, we do recommend you take readings every day. For the oral readings, you should begin on Cycle Day 2. You may elect to discontinue the oral readings once you have confirmed ovulation. For the vaginal readings, you should begin immediately after your period has ended and continue these for the remainder of your cycle.

When taking readings, should I test at the same time each day?

Yes, if possible. A variance of fewer than two hours will not significantly change results, but for the most accurate data, try to take readings at the same time each day.

Does it matter if I take a drink before taking an oral reading?

Yes. Do not eat, drink, brush your teeth, smoke or put anything in your mouth before taking your oral reading.

How come the readings seem different if I take them 2 times in a row?

The act of taking a reading impacts the electrolyte characteristics of saliva and cervical mucus.

When taking the vaginal reading, where exactly should the sensor be?

The easiest way to describe how to place the sensor is to imagine you are lying on your back. Insert the sensor vaginally just until you feel it touch the cervix. Then pull the sensor out slightly (approximately 1/4 to 1/2 inch) and lift the handle towards the ceiling, causing the sensor itself to point towards your backbone. This will drop the sensor into the cervical mucus pool, the ideal placement to get an accurate reading.

Can semen affect the results?

Yes, we recommend taking the vaginal reading prior to intercourse or waiting at least 8 hours after intercourse, while still taking the reading at your usual time.

Does the vaginal sensor confirm that I ovulated successfully?

The vaginal sensor detects the hormonal shifts that accompany ovulation. Specifically, it will identify the estrogen surge that occurs just prior to ovulation and the increase in progesterone levels that occur at the time of ovulation. In the vaginal readings, you will see a low vaginal reading just prior to ovulation followed by a sharp rise on the day of ovulation. OvaCue Mobile will identify the day that this hormonal shift occurred with a pink day, indicating that ovulation may have occurred on that day. While only a vaginal ultrasound can confirm successful ovulation with 100% accuracy, OvaCue Mobile provides valuable information about the hormonal changes that are necessary for ovulation to take place. After the pink day populates, we expect to see continued elevated vaginal readings to indicate ovulation was successful.

Cleaning and Storing OvaCue Mobile

When not in use, store your OvaCue Mobile in the carrying case provided. Please be sure to wash the oral and vaginal sensor after each use with mild soap and water.

Help

We want you to get the most from your OvaCue Mobile. For additional technical support and customer service, please contact us at (800) 367-2837 or support@ovagraph.com, or visit us at www.ovacue.com.

Warnings

- Equipment has a type BF applied part.
- If the equipment is receiving interference or causing interference, the equipment should be relocated away from other equipment.
- There is no preventive inspection or maintenance required on the system or on parts of the system.
- Environmental requirements for storage and transport:
Ambient temperature: -40C to +70C
Relative humidity: 10% to 100%
Atmospheric pressure: 500hPa to 1060hPa



Follow local governing requirements when disposing of electronic equipment.



CAUTION: General Warning - refer to accompanying documents.

